

## §212.2

*Lot number, control number, or batch number* means any distinctive combination of letters, numbers, or symbols from which the complete history of the production, processing, packing, holding, and distribution of a batch or lot of a PET drug can be determined.

*Master production and control record* means a compilation of instructions containing the procedures and specifications for the production of a PET drug.

*Material release* means the authoritative decision by a responsible person in a PET production facility to permit the use of a component, container and closure, in-process material, packaging material, or labeling in the production of a PET drug.

*PET* means positron emission tomography.

*PET drug* means a radioactive drug that exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for providing dual photon positron emission tomographic diagnostic images. The definition includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of a PET drug. "PET drug" includes a "PET drug product" as defined in this section.

*PET drug product* means a finished dosage form of a PET drug, whether or not in association with one or more other ingredients.

*PET drug production facility* means a facility that is engaged in the production of a PET drug.

*Production* means the manufacturing, compounding, processing, packaging, labeling, reprocessing, repacking, relabeling, and testing of a PET drug.

*Quality assurance* means a system for ensuring the quality of active ingredients, PET drugs, intermediates, components that yield an active pharmaceutical ingredient, analytical supplies, and other components, including container-closure systems and in-process materials, through procedures, tests, analytical methods, and acceptance criteria.

*Receiving facility* means any hospital, institution, nuclear pharmacy, imaging facility, or other entity or part of an

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entity that accepts a PET drug product that has been given final release, but does not include a common or contract carrier that transports a PET drug product from a PET production facility to a receiving facility.

*Specifications* means the tests, analytical procedures, and appropriate acceptance criteria to which a PET drug, PET drug product, component, container-closure system, in-process material, or other material used in PET drug production must conform to be considered acceptable for its intended use. Conformance to specifications means that a PET drug, PET drug product, component, container-closure system, in-process material, or other material used in PET drug production, when tested according to the described analytical procedures, meets the listed acceptance criteria.

*Strength* means the concentration of the active pharmaceutical ingredient (radioactivity amount per volume or weight at the time of calibration).

*Sub-batch* means a quantity of PET drug having uniform character and quality, within specified limits, that is produced during one succession of multiple irradiations, using a given synthesis and/or purification operation.

*Verification* means confirmation that an established method, process, or system meets predetermined acceptance criteria.

### §212.2 What is current good manufacturing practice for PET drugs?

Current good manufacturing practice for PET drugs is the minimum requirements for the methods to be used in, and the facilities and controls used for, the production, quality assurance, holding, or distribution of PET drugs intended for human use. Current good manufacturing practice is intended to ensure that each PET drug meets the requirements of the act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it is supposed to have.

### §212.5 To what drugs do the regulations in this part apply?

(a) *Application solely to PET drugs.* The regulations in this part apply only to the production, quality assurance, holding, and distribution of PET drugs.